MAY 2 4 2013

2. 510(k) Summary of Safety and Effectiveness Information

Date Prepared: November 2012
Submitted by: Merete Medical GmbH
Alt Lankwitz 102
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FDA Registration Number: 3002949614

Contact Person: Rüdiger Hilken
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Device Name: IntraBlock™ BioBall™ Hip System (IBS)

Common Name: Total hip replacement device

Classification Names: Hip Joint metal/ceramic/polymer semi-constrained, cemented or nonporous uncemented prosthesis (21 CFR 888.3353)

Product Code: LZO

Proposed Regulatory Class: Class II

Predicate Devices:
K073567 - Biolox® delta Option Ceramic Heads
K043537 - Taperloc® 12/14 Taper Femoral Components
K121563 - Corin Trift TS Hip
K001534 - Pinnacle™ Acetabular Cup
K000306 - Pinnacle™ Acetabular Cup
K093472 - Trinity Acetabular System

Device Description:
The IntraBlock™ BioBall™ Hip System (IBS) is composed of femoral stems, heads, taper adapter sleeves and acetabulum cups. The System is designed for uncemented use for either primary or revision hip arthroplasty.

The IBS stem is straight, collarless, and flat with a tapered design. The stem is manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F-136 with a proximal titanium plasma spray (TPS) coating. The stems are proportionally sized and shaped in sizes 6.25 mm to 15.00 mm to match the geometry of the femur. A lateralized version of the device is available. Both versions have a neck shaft angle of 135° and a 12/14 morse taper trunion. The Ceramic Head is made of Biolox® delta (Alumina Matrix Composite ISO 6474-2) and available in diameter 28 mm.
The taper adapter sleeves are made from titanium alloy (Ti-6Al-4V ELI) with a 12/14 morse taper trunion in the four neck lengths S, M, L and XL.

The cementless MultiCup Locking PressFit is manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F-136 with a titanium plasma spray (TPS) coating on the outer surface. It is used with a UHMWPE Inlay sized for Ø28 mm heads. 5 holes with threaded plugs give the option for an additional fixation with locking screws. The MultiCup is available in 9 different sizes ranged from 46mm, 48mm up to 62mm outer diameter.

Indications for Use
The IntraBlock™ BioBall™ Hip System (IBS) is intended for use in total hip arthroplasty.

The IBS is indicated for:
- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis
- Avascular necrosis of the femoral head
- Correction of functional deformity
- Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques
- Revision procedures where other treatment or devices have failed

The IBS is indicated for cementless use only.

Substantial Equivalence:
The IntraBlock™ BioBall™ Stems, MultiCup™ Locking PressFit, Femoral Heads and Titanium Taper Adapter Sleeves are technologically similar to the predicate devices.

Legally marketed Devices to which substantial Equivalence is claimed
K073567 - Biolox® delta Option Ceramic Heads
K043537 - Taperloc® 12/14 Taper Femoral Components
K121563 - Corin Trift TS Hip
K001534 - Pinnacle™ Acetabular Cup
K000306 - Pinnacle™ Acetabular Cup
K093472 - Trinity Acetabular System

Non-Clinical Performance Data:
Non-clinical testing and analysis were provided, including mechanical testing and coating characterization. Mechanical testing included distal and proximal fatigue testing of the worst case consistent with the „Guidance for Industry and FDA staff Non-Clinical Information for femoral Stem Prostheses". Range of Motion analysis was also performed. The TPS coating underwent characterization per FDA´s „Guidance for Industry on Testing of Metallic Plasma Sprayed Coatings on Orthopaedic Implants to support reconsideration of Post Market Surveillance Requirements". The Modular connection analysis including fretting and corrosion were also performed as well as static compression testing consistent with the "Guidance document for the preparation of premarket notifications for ceramic ball hip systems". Furthermore the connections between the stem, the adapter and the head, as well as the liner locking mechanism were tested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 24, 2013

Merete Medical GmbH
% Mr. Emanuel Anapliotis
President
Alt-Lankwitz 102
Berlin 12247
Germany

Re: K123619
Trade/Device Name: IntraBlock™ BioBall™ Hip System (IBS)
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Regulatory Class: Class II
Product Code: LZO
Dated: April 18, 2013
Received: April 24, 2013

Dear Mr. Anapliotis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For Erin D Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications for Use Statement

Indications for Use

510(k) Number (if known): K123619

Device Name: IntraBlock™ BioBall™ Hip System (IBS)

Indications for Use:
The IntraBlock™ BioBall™ Hip System (IBS) is intended for use in total hip arthroplasty.

The IBS is indicated for:
- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis,
- Avascular necrosis of the femoral head,
- Correction of functional deformity,
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- Revision procedures where other treatment or devices have failed.

The IBS is indicated for cementless use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices